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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

TruFlow™ Dialysis Catheters

July 8, 2002

I. GENERAL INFORMATION

Applicant's Name and Address:	Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa J. Stone Manager, Regulatory Affairs
Common/Usual Name:	Dialysis Catheter
Proprietary Name:	TruFlow™ Long-term and Short-term Dual-lumen Dialysis Catheters
Equivalence Device Comparison:	MedComp Hemo-Flow™ Dual Lumen Dialysis Catheter and MedComp Duo-Flow™ Dual Lumen Catheter

II. DEVICE DESCRIPTION

The catheters are long- and short-term dual lumen polyurethane dialysis catheters with D-shaped inner lumens and a staggered tip. Long-term catheters include a pre-attached in-growth cuff. Various product configurations will be offered, including IJ, straight and pre-curved catheters. Catheters will be offered in multi-unit packaging and with accessory components.

III. INTENDED USE OF THE DEVICE

TruFlow™ Long-term Dual-lumen Hemodialysis Catheter is indicated for use when therapy requires long-term vascular access for hemodialysis and apheresis. The TruFlow™ Short-term Dual-lumen Hemodialysis Catheter is indicated for use when therapy requires acute hemodialysis and apheresis.

IV. DEVICE COMPARISON

The technological characteristics of the TruFlow™ Dialysis Catheters are substantially equivalent to the predicate device in terms of intended use, instructions for use, material type, device specification, manufacturing process and method of sterilization.

V. SUMMARY OF STUDIES

A. Functional Testing

In-vitro testing was conducted on the TruFlow™ Dialysis Catheters.

Biocompatibility testing was also conducted on the catheters.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the TruFlow™ Dialysis Catheters due to their similarity in materials, design and function to the Medcomp Dialysis Catheters.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the TruFlow™ Dialysis Catheters function according to specifications and the materials used in the device are biocompatible. Therefore, this product is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2003

Ms. Lisa Stone
Manager, Regulatory Affairs
Deltec, Inc.
1265 Grey Fox Road
ST PAUL MN 55112

Re: K022221
Trade/Device Name: TruFlow™ Long-term and Short-term Dual-lumen Dialysis Catheters
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 MPB
Regulatory Class: III
Product Code: 78 MSD
Dated: October 31, 2002
Received: November 1, 2002

Dear Ms. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Iodine Swabsticks, Povidone Iodine Ointment, and Lidocaine HCl, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html

Sincerely yours,

David A. Ragsdale

for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022221

Device Name: TruFlow™ Long-term and Short-term Dual-lumen Dialysis Catheters

Indications for Use:

"TruFlow™ Long-term Dual-lumen Hemodialysis Catheter is indicated for use when therapy requires long-term vascular access for hemodialysis and apheresis. The TruFlow™ Short-term Dual-lumen Hemodialysis Catheter is indicated for use when therapy requires short-term vascular access for acute hemodialysis and apheresis.

TruFlow™ Long-term Dual-lumen Hemodialysis Catheters can be inserted percutaneously in the internal jugular, in the subclavian vein as required, or the femoral vein.

TruFlow™ Short-term Dual-lumen Hemodialysis Catheters can be inserted percutaneously in the internal jugular, in the subclavian vein as required, or the femoral vein."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1 OR Over-The Counter Use _____
(Per 21 CFR 801.109)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022221